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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
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ART UNIT	PAPER NUMBER
1633	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/528,748	JUNGHANS ET AL.	
	Examiner	Art Unit	
	MARIA LEAVITT	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 November 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-13 and 15-21* is/are pending in the application.

4a) Of the above claim(s) *4,5,13 and 15-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-3,6-12 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Status of claims. Claims 2-13 and 15-21 are pending and not claims 2-21 as Applicants state at page 7 of Remarks. Claims 2, 3, 6-12 have been amended, claim 1 has been canceled, claim 21 has been added and claims 4, 5, 13, 15-20 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim by Applicants' amendment filed on 11-25-2008. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.
3. Therefore, claims 2, 3, 6-12 and 21 are currently under examination to which the following grounds of rejection are applicable.

Withdrawn Objection/Rejections in response to Applicants' arguments or amendments:

Claim objection

In view of Applicants' amendment of claims 2, 3, 6-12 to insert the proper definite articles, objection the claims has been withdrawn.

In view of Applicants' amendment of claim 8 to recite the proper antecent bases for the phrase "double stranded region", objection to claim 8 has been withdrawn.

In view of Applicants' cancellation of claim 1, objection to claim 1 is rendered moot.

Objections/Rejections maintained in response to Applicants' arguments or amendments:

Specification objection

The specification remains objected in view of Applicants' amendment of the specification at page 20, line 10, and insertion of the phrase -NCBI Genbank-. The codon usage table for cats obtained from the codon usage database appears to constitute essential material and may be added into the specification by amendment (See 37 CFR 1.57 (a) through (g)). The incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference, if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. 37 CFR 1.57(f).

Notice To Comply with Sequence Rules For Patent Applications Containing nucleotide Sequence And/Or Amino acid Sequence Disclosures

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821 through 1.825. However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below.

Specifically the application fails to comply with CFR 1.821(d), which states:

(d) Where the description or claims of a patent application discuss a sequence

> that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, reference must be made to the sequence **by use of the sequence identifier, preceded by "SEQ ID NO:"** in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application [emphasis added].

Furthermore, the MPEP 2422 under the heading Nucleotide and/or Amino Acid Sequence Disclosures in Patent recites "

37 CFR 1.821. Nucleotide and/or amino acid sequence disclosures in patent applications.
(a) Nucleotide and /or amino acid sequences as used in § § 1.821 through 1.825 are interpreted to mean an unbranched sequence of **four or more amino acids** or an unbranched sequence of ten or more nucleotides.

Specifically, claim 11 recites a peptide sequence comprising seven amino acid residues that has not been described or named with a proper identifier.

Full compliance with the sequence rules is required in response to this Office Action. A complete response to this office action should include both compliance with the sequence rules, which include amendment of the specification and claims to include SEQ ID NOS., and a response to the rejections set forth below. Failure to comply with **both** these requirements in the time period set forth in this office action will be held non-responsive.

Claim Rejections - 35 USC § 102

Claims 6 and 12 remain rejected and new claim 21 is rejected under 35 USC. 102(b) as being anticipated by Khan et al., (U.S. Patent No. 6,248,582; Date of Patent June 19, 2001).

New claim 21 is broadly interpreted as a DNA expression construct comprising a promoter sequence operable in Felidae comprising a mutated nucleotide sequence encoding at

least for a Gag or Env protein which is not identical to the wild type Gag or Env of FeLV and said encoded protein is not required to be functional.

Response to Applicant Arguments as they apply to rejection of Claims 6, 12 and claim 21 under - 35 USC § 102

At page 9 of Remarks, Applicants essentially argue that the instant invention is drawn to DNA expression cassettes wherein the mutated *pol* gene is not codon optimized and there is not splice donor/ acceptor site deletion. In addition, Applicants allege that the mutations disclosed in the Kahn Patent are non-functional mutations and that the mutations are not directed to the *gag* and *env* genes but to the *pol* gene and its integrase function. Such is nor persuasive.

As an initial matter, the examiner notes that the instant claims do not place any limitation in relation to whether the claimed nucleotide sequence is codon optimized or whether there is a deletion of the splice/donor acceptor site. Indeed none of these limitations are recited in the claims. In contrast, the claims are broadly interpreted as encompassing a mutated nucleotide sequence encoding at least for a Gag or Env protein which is not identical to the wild type Gag or Env of FeLV and said encoded protein is not even required to be functional (e.g., to have the activity of a Gag or Env protein). The application does not define the minimum requirements of a mutated nucleotide sequence. Therefore, a mutated nucleotide sequence read, for example, on any two or more nucleotides that might be comprised in a *gag* or an *env* gene (e.g., CGA, AGA, CGU). As such conservative modified variations as described at col. 6, lines 33, referred by Applicants, are mutated nucleotide sequences encoding at least for a portion of a Gag or a Env protein.

At page 9 of remarks, Applicants refer to Examples 6 as one example of a truncated *env* gene lacking 150 bp. Applicants contend that the truncated *env* gene is not a mutated nucleotide sequence but rather a shortening of 150 base pairs. Such is not persuasive.

Note that the specification does not provide a closed definition of the word "mutation", accordingly, mutations are broadly interpreted as deletions, substitutions or insertions within certain regions of the *gag* or *env* gene. Accordingly, the truncated *env* gene disclosed in Examples 6 of the Kahn Patent reads on the claimed DNA expression construct.

Claim Rejections - 35 USC § 103

Claims 9-11 remain rejected and claims 7, 8 and 21 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over Khan et al., US 6,248,582 (Date of Patent June 19, 2001) in view of Schirmbeck et al., (J Mol Med. 2001; pp. 343-50).

Response to Applicant Arguments as they apply to rejection of Claims 7-11 and 21 under 35 USC § 103

At page 10 of Remarks, in relation to the Schirmbeck et al., publication, Applicants allege that Schirmbeck teaches an expression construct comprising a HbsAgAY nucleotide sequence with a MIDGE vector conjugated to the nuclear localization peptide comprising the claimed peptide sequence PKKKRKV. Applicants contend that the DNA construct of Schirmbeck is completely different to the biological system of the invention because the instant construct infects cat cells and not human cells. Moreover, Applicants argue that the HbsAgAY nucleotide

sequence would not obviated the instantly claimed codon optimized *gag* and *env* genes. Such is not persuasive.

The instant claims are product claims. If vaccine efficiency is improved by a DNA construct comprising a minimalistic immunologically defined gene expression vector (MIDGE) linked to a DNA comprising a HbsAgAY antigen-coding sequence under the control of an operable promoter and conjugated to the nuclear localization peptide as taught by Schirmbeck et al, said construct should be reasonably expected to improve vaccine efficiency in cats when using a nucleotide sequence encoding an immunogenic FeLV antigen for the same reasons it improves HbsAgAY antigenicity in humans as both human and cats are mammals with related humoral and cellular immune responses. It is also noticed that the claim 21 recites "at least one Feline Leucosis virus nucleotide sequence which is mutated as compared to the wildtype" . There is no limitation placed in the claims as written that the nucleic acid encoding a Gag or a Env protein is codon optimized. Hence the argument is not persuasive as they argue limitations that are not present in the claims.

Claim 3 remains rejected and claim 2 is newly rejected under 35 U.S.C. 103(a) as being unpatentable over Khan et al., US 6,248,582 (Date of Patent June 19, 2001) in view of Schirmbeck et al., (J Mol Med. 2001 ; pp. 343-50) as applied to claims 7-11 and 21 above and further in view of Shiver et al., (US Patent. 6,696,291 (Date of Patent Feb. 24, 2004), Laprevotte et al., (1984, J. Virol. , pp. 884-894 Genbank Accession No., K01803, FeLV gag cDNA) and Gardner-Arnstein feline leukemia oncovirus codon usage (www.kazusa.or.ip/codon, of record).

Note that amended claim 2 reads on DNA expression constructs comprising a promoter sequence operable in Felidae and at least one Feline Leucosis virus nucleotide sequence encoding for at least Gag and Env protein at least 98% homologue to the wild type sequence protein.

Response to Applicant Arguments as they apply to rejection of Claims 2 and 3 under 35 USC § 103.

At pages 11-12 of Remarks, Applicants essentially argue that the Examiner has used multiple references indicating the weakness of the rejection. Moreover, Applicants contend that "Shiver does not teach use of a codon-optimized *env* gene", that Laprevotte discloses nucleotide sequences that are codon optimized for HIV but not necessarily from FeLV and that the combination of the claimed nucleotide sequence of SEQ ID NO:5, which is a commonly used sequence known in the art and the disclosure of feline leukemia oncovirus codon usage would not obviate the instant invention. Such is not persuasive.

At the outset the examiner strenuously disagree with the Applicants' position that it would have been unobvious to a skilled artisan to arrive at the instant invention through the combination of Khan, Schirmbeck, Shiver , Laprevotte, and Gardner-Arnstein feline leukemia oncovirus codon usage (www.kazusa.or.ip/codon, of record). In response to applicants' argument that the examiner has combined an excessive number of references, reliance on a large number of references in a rejection does not, without more, weigh against the obviousness of the claimed invention. See *In re Gorman*, 933 F.2d 982, 18 USPQ2d 1885 (Fed. Cir. 1991). It is also noted that amended claim 3 is directed to a DNA construct containing the nucleotide sequence of SEQ ID NO. 5 "which has been mutated in the course of codon optimization". The limitation reciting,

"mutated in the course of codon optimization " is a process limitation which defines the claimed product by the process of its manufacture and is construed based the identifiable, distinctive structural characteristic imparted to the final product by the manufacturing steps. In the instant claim 3, reciting a method step adds no structural limitations to the claimed product of a nucleotide sequence of SEQ ID No. 5. As the complete genome of the *gag* gene of FeLV was used and known in the art at the time the invention was made as well as the most prevalent codons highly expressed in cat genes, as taught by Gardner-Arnstein feline leukemia oncovirus codon usage, it would have been *prima facie* obvious to optimize the wild type FeLV nucleotide coding for FeLV *gag* and *env* proteins according to the most prevalent codons highly expressed in cat to create a more efficient DNA vaccine resulting in the nucleotide of SEQ ID NO: 5 or in a nucleotide sequence encoding for at least Gag and Env protein at least 98% homologues to the wild type sequence protein. The motivation to combine the references is in part provided by Shiver who teaches the benefits of codon usage achieving high expression levels of exogenous *gag* and *env* HIV-1 genes in transformed host organisms.

New grounds of rejection/objection necessitated by applicants' amendment

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 6, 7 and 21 are rejected under 35 USC. 102(b) as being anticipated by Paoletti E (WO9215672, Date of publication 17-Sep-1992; see Result 5, SCORE Search Results Details for Application 10528748 and Search Result 20080609_130757_us-10-528-748-5.rng). **This is a new rejection necessitated by amendment of the claims in the responses filed 11-25-2008.**

Paoletti E et al., teaches a 3674bp nucleotide sequence of Fig. 27 which encodes the feline leukemia virus (FeLV-A) *gag* gene, said nucleotide sequence having a nucleotide homology of 52.7% homology to the nucleotide sequence of instantly disclosed SEQ ID NO: 5 (see Result 5, SCORE Search Results Details). In addition, Paoletti E teaches constructs comprising the vaccinia virus H6 promoter and the FeLV-A pol gene. Furthermore, Paoletti E. et al., discloses that the construct is use as a vaccine in cats (p. 82, last paragraphs). Antibodies elicited against the product of the construct comprising a promoter and nucleotide encoding the feline leukemia virus (FeLV-A) *gag* gene clearly indicate that the promoter is operably linked to the FeLV-A *gag* gene sequence (p. 98, Table12).

Thus by teaching all the claims limitations, Paoletti et al., anticipate the instant invention.

Claim Rejections - 35 USC § 112- Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 21 and dependent claims 2, 3 and 6-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the

claim language. **This is a new rejection necessitated by amendment of the claims in the responses filed 11-25-2008.**

Claim 21 is indefinite in the reciting "said nucleotide sequence encodes a protein" in lines 7-8. There is no antecedent basis for "said nucleotide sequence encodes a protein" in the claim as the nucleotide sequence encoding at least one of a structure protein "gag" and a membrane protein "env" is a "mutated nucleotide sequence as recited in line 6 of claim 21.

Additionally, claim 21 is vague and indefinite in that the metes and bounds of the phrase "no open or hidden or acceptor sequences" are unclear. The specification does not provied a closed definition of the phrase "no open or hidden sequence". Therefore, the skilled artisan would not readily apprise of the metes and bounds of " no open or hidden sequence " nor how to assess such. It is unclear how to interpret what is considered "no open or hidden sequence " and inasmuch as it is not a recognized term and not defined in the specification.

Claims 2, 3 and 6-12 are indefinite insofar as they depend from claim 21.

Claim 8 which depends on claim 21 recites "the immunizing polypeptide". However, claim 21 only refers to "encodes a protein". Thus there is not a proper antecedent bases for said immunizing polypeptide in claim 21. As such, the metes and bounds of the claims cannot be determined.

Claim Objections

The amendment to the claims filed on 11-25-2008 does not comply with the requirements of 37 CFR 1.121(c) because changes in the texts of currently amended claims 2, 3 and 6-12 filed

on 12-18-2007 was not completely marked with respect to the previously presented claim 2-12, filed on 03-13-2006. Specifically, currently amended claims 2, 3 and 6-12 have not been striked-through to properly mark the changes. Amendments to the claims filed on or after 03-13-2006 must comply with 37 CFR 1.121(c) which states:

(B) **Markings to Show the Changes**: All claims being currently amended must be presented with markings to indicate the changes that have been made relative to the immediate prior version. The changes in any amended claim must be shown by strike-through (for deleted matter) or underlining (for added matter) with 2 exceptions: (1) for deletion of five or fewer consecutive characters, double brackets may be used (e.g., [[eroor]]); (2) if strike-through cannot be easily perceived (e.g., deletion of number "4" or certain punctuation marks), double brackets must be used (e.g., [[4]]). As an alternative to using double brackets, however, extra portions of text may be included before and after text being deleted, all in strike-through, followed by including and underlining the extra text with the desired change . An accompanying clean version is not required and should not be presented. Only claims of the status "currently amended" or "withdrawn" will include markings.

For the purpose of compact prosecution claims 2, 3 and 6-12 have been interpreted as dependent on claim 21.

Claim 3 is objected to because of the following informalities: Claim 3 is directed to a DNA construct containing the nucleotide sequence of SEQ ID NO. 5,"which has been mutated in the course of codon optimization". The recited limitation "mutated in the course of codon

optimization" is a process limitation which adds no structural limitations to the claimed product of nucleotide sequence of SEQ ID No. 5. Appropriate correction is required.

Conclusion

Claims 2, 3, 6-12 and 21 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria Leavitt whose telephone number is 571-272-1085. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

/Maria Leavitt/

Maria Leavitt, PhD
Examiner, Art Unit 1633